Oridion Medical 1987 Ltd.
Dalia Givony
Regulatory and Clinical Affairs Manager
7 Hamarpe Street, P.O. Box 45025
Jerusalem, 9777407 Il

Re: K181624
Trade/Device Name: Microstream Advance Neonatal-Infant Nasal Filter Line with O2 Tubing,
Microstream Advance Pediatric Oral-Nasal Filter Line with O2 Tubing,
Microstream Advance Adult Oral-Nasal Filter Line with O2 Tubing,
Microstream Luer Adult Oral-Nasal Sampling Line
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: February 5, 2019
Received: February 8, 2019

Dear Dalia Givony:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd D. Courtney
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for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

001_Indications for Use Statement

(*This document is not confidential)*

June 18, 2018

Indications for Use:

- Microstream™ Advance Neonatal-Infant Nasal Filter Line with O2 Tubing
- Microstream™ Advance Pediatric Oral-Nasal Filter Line with O2 Tubing
- Microstream™ Advance Adult Oral-Nasal Filter Line with O2 Tubing

Used to conduct a sample of the subject's breathing to a gas measurement device (capnograph) while simultaneously administering supplemental oxygen projected near the nose and mouth for inhalation. The device is to be used with monitors using Microstream™ technology.

- Microstream™ Luer Adult Oral-Nasal Sampling Line

Used whenever the physician needs to collect a sample of the patient's breathing to measure CO2 with a capnograph while simultaneously administering supplemental oxygen near the nose and mouth for inhalation.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

510 (k) Summary

510(k) Number: K181624

DATE THIS SUMMARY WAS PREPARED
March 14, 2019

Products Trade Name:
Microstream™ Advance Neonatal-Infant Nasal Filter Line with O2 Tubing
Microstream™ Advance Pediatric Oral-Nasal Filter Line with O2 Tubing
Microstream™ Advance Adult Oral-Nasal Filter Line with O2 Tubing
Microstream™ Luer Adult Oral-Nasal Sampling Line

Common:
Non-Intubated CO2 Sampling Line

Establishment Registration Number
8044004

Establishment Address:
Oridion Medical 1987 Ltd.
7 Hamarpe Street,
POB 45025, 9777407 Jerusalem

Contact Person:
Dalia Givony
Regulatory & Clinical Consulting
+972-8-9721157
dalia@daliag.com

Classification:
Product Classification: 73CCK Class II

This device is a capnograph accessory. It is classified as follows:

21 CFR 868.1400, carbon dioxide analyzer.

Predicate Devices:

O2/CO2 NASAL FILTERLINE cleared under K010024

MICROSTREAM O2/CO2 ORAL NASAL FILTERLINE cleared under K011536

MAC-Line O2/CO2 ORAL NASAL CANNULA SAMPLE LINE cleared under K013845

Device description:

Similar to their predicates, the Microstream non-intubated sampling line/Filter Line family is intended to conduct CO2 from the patient's breath to a gas measurement device (Capnograph) while simultaneously administering supplemental oxygen projected near the nose and mouth for inhalation (when connected to an O2 source).

The proposed devices are a modification of their predicates' material compounds (not made with DEHP or PHT materials), a change of dryer location to off the patient's face, and the integration of softer face-contacting tubes, mainly to enhance patient comfort, increase flexibility and reduce smell.

The proposed devices are sampling lines which are intended to be used with Capnograph monitors using Microstream technology. These sampling lines incorporate a luer connector with a recognition system:

- Microstream™ Advance Neonatal-Infant Nasal Filter Line with O2 Tubing
- Microstream™ Advance Pediatric Oral-Nasal Filter Line with O2 Tubing
- Microstream™ Advance Adult Oral-Nasal Filter Line with O2 Tubing

In addition, this sampling line which is intended to be used with any Capnograph monitor is proposed:

- Microstream™ Luer Adult Oral-Nasal Sampling Line

Intended Use/Indications for Use:

- Microstream™ Advance Neonatal-Infant Nasal Filter Line with O2 Tubing
- Microstream™ Advance Pediatric Oral-Nasal Filter Line with O2 Tubing
- Microstream™ Advance Adult Oral-Nasal Filter Line with O2 Tubing

Used to conduct a sample of the subject’s breathing to a gas measurement device (capnograph) while simultaneously administering supplemental oxygen

projected near the nose and mouth for inhalation. The device is to be used with monitors using Microstream™ technology.

- Microstream™ Luer Adult Oral-Nasal Sampling Line

Used whenever the physician needs to collect a sample of the patient's breathing to measure CO2 with a capnograph while simultaneously administering supplemental oxygen near the nose and mouth for inhalation.

Substantial equivalence table

Feature	Predicate device: K010024 O2/CO2 NASAL FILTERLINE	Microstream™ Advance Neonatal-Infant Nasal Filter Line with O2 Tubing	Predicate device: K011536 MICROSTREAM O2/CO2 ORAL NASAL FILTERLINE	Microstream™ Advance Pediatric Oral-Nasal Filter Line with O2 Tubing	Microstream™ Advance Adult Oral-Nasal Filter Line with O2 Tubing	Predicate device: K013845 MAC-Line O2/CO2 Oral Nasal Cannula sample line	Microstream ™ Luer Adult Oral-Nasal Sampling Line
Intended population (non-intubated)	Adults and pediatrics	Neonatal-Infant	Adult, intermediate or pediatric	Pediatric	Adult	Adult, intermediate or pediatric	Adult
Single patient use	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Patient interface	Nasal Cannula	Same as K010024	Oral Nasal Cannula	Same as K011536	Same as K011536	Oral Nasal Cannula	Same as K013845
Biocompatibility	ISO 10993-1	ISO 10993-1 ISO 18562-1	ISO 10993-1	ISO 10993-1, ISO 18562-1	ISO 10993-1 ISO 18562-1	ISO 10993-1	ISO 10993-1 ISO 18562-1
Dehumidifier/ Dryer	-	+	-	+/-	+/-	-	-
Rise time	≤200 msec @50ml/min sample flow rate, sea level, RT minimal background= 50msec	≤260 msec @ 50ml/min sample flow rate, sea level, RT minimal background= 50msec	≤200 msec @ 50ml/min sample flow rate, sea level, RT minimal background= 50msec	≤200 for 2m; ≤260 for 4m @50ml/min sample flow rate, sea level, RT minimal background= 50msec	200 msec @ 50ml/min sample flow rate, sea level, RT minimal background=50msec	≤200 msec @ 50ml/min sample flow rate, sea level. ≤100msec @ 180ml/mi. RTbackground = 50msec	200 msec @ 50ml/min sample flow rate, sea level. ≤100msec @ 180ml/min

Feature	Predicate device: K010024 O2/CO2 NASAL FILTERLINE	Microstream™ Advance Neonatal-Infant Nasal Filter Line with O2 Tubing	Predicate device: K011536 MICROSTREAM O2/CO2 ORAL NASAL FILTERLINE	Microstream™ Advance Pediatric Oral-Nasal Filter Line with O2 Tubing	Microstream™ Advance Adult Oral-Nasal Filter Line with O2 Tubing	Predicate device: K013845 MAC-Line O2/CO2 Oral Nasal Cannula sample line	Microstream ™ Luer Adult Oral-Nasal Sampling Line
							RT background = 50msec
Pressure Drop-	CO2 sampling set: 40mbar@ 50 ml/min, sea level. O2 line: ≤135mBar @ 8L/min, at sea level.	CO2 line: ≤75[mbar] @ 50 ml/min, sea level. O2 line: 225mBar@ 3L/min, at sea level.	CO2 sampling set: 40mbar@ 50 ml/min, sea level. O2 line: ≤135mBar @ 8L/min, at sea level.	CO2 line: ≤75[mbar] @ 50ml/min; sea level; max 4m length. O2 line: ≤110mBar @ 5L/min, at sea level	CO2 line: ≤75[mbar] @ 50[ml/min; sea level. O2 line: ≤110mBar @ 5L/min, at sea level.	CO2 line: ≤70mbar @ 180ml/min. sea level. O2 line: ≤135mBar @ 8L/min, at sea level	CO2 line: ≤70[mbar] @ 180ml/min sea level. O2 line: ≤80mBar @ 5L/min, at sea level
Leak Tightness	Was not provided under the 510k submission	≤2[mbar/sec] @ 100[mbar] vacuum.	≤10mbar/sec	≤2[mbar/sec] @ 100[mbar] vacuum	≤2[mbar/sec] @ 100[mbar] vacuum.	Was not provided under the 510k submission	≤2[mbar/sec] @ 100[mbar] vacuum
Tensile Strength	Was not provided under the 510k submission	CO2 line: Withstand a pull test of 1kg. O2 line: Withstand a pull test of 2kg	Was not provided under the 510k submission	Withstand a pull test of 2kg.	Withstand a pull test of 2kg.	Was not provided under the 510k submission	Withstand a pull test of 2kg.

Clinical/ Non-Clinical:

Biocompatibility was assessed according to ISO 10993, ISO 18562-1 and FDA guidance. The devices are intended for prolonged use (>24 hours-30 days) and composed of components for exhaled breath (CO2 tubing, dehumidifier), and components for inhaled breath (O2 delivery tubing, cannula, connectors).
Components for exhaled breath (with tissue contact) were tested for Cytotoxicity, Sensitization, and Intracutaneous. Components for inhaled breath (externally communicating, indirect contact with tissue in the patient respiratory pathway) were tested for Cytotoxicity, Sensitization, Intracutaneous, Acute Systemic Toxicity, Pyrogenicity, Particulate, and Volatile Organic Compounds.

Performance data:

Bench testing was conducted to ensure the devices' performance and to demonstrate substantial equivalence to the predicates. This includes mainly pressure drop, tensile strength, leak tightness, rise time, resistance to kinking of the O2 Line, resistance to kinking of CO2 line, and O2 and CO2 connector mechanical testing.

Conclusion:

Biocompatibility testing as well as performance bench testing shows that the subject devices are substantially equivalent to their predicates without raising different questions of safety and effectiveness.